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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,521	11/01/2001	Timothy Samuel Girton	760-35 CIP	6660

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,521

Applicant(s)

GIRTON ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004 and 18 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 22 requires an extractable polymer in a particulate form, forming an IPN with PTFE. The *only* mention of interpenetrating polymer networks (IPN) is an IPN formed of PTFE and **siloxane**. Siloxane was not found to be disclosed to be in a particulate form, further, there is no disclosure as to how an IPN is formed in the first place. Also, there was no disclosure found combining an IPN having particles. Although particulate form is disclosed for polymers listed in Table 1, it is not disclosed as a means for forming an IPN of siloxane (not even listed in the table) and PTFE.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell (USPN 4,764,560, cited in previous office action). Referring to claims 1 and 3, Mitchell discloses a medical device, specifically a vascular graft (tubes for arteries and veins, col.1, lines 60-62; any medical application, col.3, lines 35-38) comprising a tubular extrudate (col.6, lines 45-53; Table 3, 5) comprising an interpenetrating polymer network (col.1, lines 11-13, 63-66; col.6, lines 42-48) comprising a non-expanded PTFE matrix (extruded *rather than stretching*, first polymer col.6, lines 42-53) having distributed therein discrete domains of an extractable polymeric material (second polymer, col.6, lines 47-48, which is *capable* of being extracted, as shown in Table 5, therefore it is *extractable*), wherein upon exposure to a dissolving medium or degradation temperature, the polymer is extracted from the matrix (Table 5; col.10, lines 52-63) to create pores in the tubular extrudate (extraction of the polymer will create pores inherently, since when something is removed, void space remains, also, the since applicant performs the same method and it forms pores, therefore Mitchell's will also form pores, since the same method is occurring).

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Referring to claim 21, Mitchell discloses the extractable polymer to comprise silicone (col.10, lines 57-59).

Referring to claim 24, Mitchell discloses an implantable extrudate comprising a non-expanded PTFE resin (first polymer, col.6, lines 45-46, 52-53) and a polymeric component (second polymer, col.6, lines 47-48) which is incompatible with the non-expanded PTFE resin, wherein discrete domains of the polymeric component are distributed throughout the resin and are extractable therefrom (polymer is *capable* of being extracted, as shown in Table 5, therefore it is *extractable*).

Claims 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Landi (USPN 5,141,522, cited by applicant in IDS). Referring to claim 23, Landi discloses an implantable extrudate (col.1, lines 37-42), comprising a tubular extrudate (col.1, lines 55-58) comprising a non-expanded PTFE matrix (col.1, lines 54-55) and a plurality of pores distributed throughout the PTFE matrix, the pores having a shape defined by an extracted polymeric material (col.3, lines 42-52).

Referring to claim 24, Landi discloses an implantable extrudate (col.1, lines 37-42) comprising a non-expanded PTFE resin (col.1, lines 54-55; col.3, lines 42-44) and a polymeric component (thermoplastic, PMMA; col.3, line 47), which is incompatible with the non-expanded PTFE resin, wherein discrete domains of the polymeric component are distributed throughout the resin and are extractable therefrom (col.6, lines 42-53, 64-66).

Claims 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Zilla et al. (USPN 6,540,780 B1, cited in previous office action). Referring to claim 23, Zilla discloses an implantable extrudate (col.1, line 12; col.2, lines 61-62), comprising a tubular extrudate (col.7, lines 46-50) comprising a non-expanded PTFE matrix (PTFE fibers form a matrix, col.4, lines 1-8; and PTFE graft material may form the matrix, col.10, lines 10-11) and a plurality of pores distributed throughout the PTFE matrix, the pores having a shape defined by an extracted polymeric material (col.6, lines 61-67).

Referring to claim 24, Zilla discloses an implantable extrudate (col.1, line 12; col.2, lines 61-62) comprising a non-expanded PTFE resin (PTFE fibers form a matrix, col.4, lines 1-8; and PTFE graft material may form the matrix, col.10, lines 10-11) and a polymeric component (col.3, lines 46-49; col.4, lines 55-67), which is incompatible with the non-expanded PTFE resin, wherein discrete domains of the polymeric component are distributed throughout the resin and are extractable therefrom (col.6, lines 61-67).

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk (USPN 4,657,544, cited by applicant in IDS). Pinchuk discloses an implantable extrudate (10; fig.1), comprising a tubular extrudate (col.2, lines 59-61) comprising a non-expanded PTFE matrix (col.4, line 8) and a plurality of pores (16) distributed throughout the PTFE matrix, the pores having a shape defined by an extracted polymeric material (the pores 16 exist, from an extracted material, salt, however the method of forming the pores or what is used to form them, has not been given patentable weight, because this is a product claim and since the end product is the

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same as the applicants, the method of producing the end product is a method step and is not taken into account).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (USPN 4,764,560, cited in previous office action) in view of Dereume et al. (USPN 5,639,278, cited in previous office action). Mitchell discloses a medical device (tubes for arteries and veins, col.1, lines 60-62; any medical application, col.3, lines 35-38) comprising a tubular extrudate (col.6, lines 45-53; Table 3, 5), commonly known as a graft comprising an IPN (col.1, lines 11-13, 63-66; col.6, lines 42-48), which comprises a non-expanded PTFE matrix (extruded *rather than stretching*, first polymer col.6, lines 42-53) having domains of an extractable polymeric material (second polymer, col.6, lines 47-48, which is *capable* of being extracted, as shown in Table 5, therefore it is *extractable*). Mitchell does not teach however, a stent combined with a graft. Dereume teaches combining an axially positioned stent (22) combined with a graft (23 or 24), in order to provide increased support by the stent, enhanced tissue ingrowth by the graft, and means to cover an aneurysm in an artery or vein (col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent with a graft, with Mitchell's type of

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extruded graft made of porous PTFE, in order to provide an endoprosthesis that supports an artery or vein, covers an aneurysm, enhances tissue ingrowth, etc. enhancing the overall biocompatibility of the prosthesis.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (USPN 4,764,560, cited in previous office action). Mitchell discloses a medical device (tubes for arteries and veins, col.1, lines 60-62; any medical application, col.3, lines 35-38) comprising a tubular extrudate (col.6, lines 45-53; Table 3, 5) comprising an interpenetrating polymer network (col.1, lines 11-13, 63-66; col.6, lines 42-48) comprising a non-expanded PTFE matrix (extruded *rather than stretching*, first polymer col.6, lines 42-53) having distributed therein discrete domains of an extractable polymeric material (second polymer, col.6, lines 47-48, which is *capable* of being extracted, as shown in Table 5, therefore it is *extractable*), wherein upon exposure to sufficient dissolving medium or degradation temperature, the extractable polymeric material is extracted from the matrix (Table 5; col.10, lines 52-63), creating pores (extraction of the polymer will create pores inherently, since when something is removed, void space remains, also, the since applicant performs the same method and it forms pores, therefore Mitchell's will also form pores, since the same method is occurring). Although Mitchell discloses discrete domains of a polymeric material, Mitchell is silent to mention the size of the polymeric particles. It would have been an obvious matter of design choice to have a particle size of 5-100um, since such a modification would have involved a mere change in size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER